containing said DNA"; Invention II (claims 100-104) drawn to "a method of making a DNA sequence"; Invention III (claims 110-114 and 120-124) drawn to "a protein"; and Invention IV (claims 115-119[3]) drawn to "a method of making a protein." (Paper No. 31 at 2.)

The Examiner then asserted that:

> Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 100-104, 110-124 are withdrawn from consideration as being directed to a non-elected inventions. (*Id.* at 3.)

The Examiner further asserted that:

> This application contains claims directed to the following patentably distinct species of the claimed invention:
> A recombinant DNA wherein the human Ig is selected from the group consisting of IgG, IgA, IgM or IgE. (*Id.*)

The Examiner then required the applicant to "elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable." (*Id.*) Moreover, the Examiner required that "[i]f applicant elects IgG, then a further species election is required between IgG1 or IgG3." (*Id.*)

Reconsideration and withdrawal of the restriction is respectfully requested. In accordance with restriction practice, and solely for examination purposes, IgG1 is elected for prosecution on the merits, with traverse.

Contrary to the Examiner's assertion, claims 100-104 and 110-124 are not barred by an alleged "constructive election." Constructive election occurs only when the applicant presents an amendment which results in independent or distinct groups of

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incorrect the Examiner is asked to reissue the restriction requirement to clearly set forth which claims are found in each group.

[3] Claims 115-119 are not explicitly recited as belonging to Invention IV, however, they are the only claims which are unaccounted in the other Inventions, and they are drawn to methods of making a protein. According, it is assumed that claims 115-119 are considered part of Invention IV. If this assumption is

claims, which if examined together, would impose a serious burden on the Examiner without the election. 37 C.F.R. § 1.145 and MPEP §§ 806-808.02 and 821.03 (8th Ed., Rev. 1, February 2003, pp. 800-39 to 800-48 and 800.63).

Claim 68 recites:

> A DNA sequence which encodes a chimeric protein and comprises (i) a first DNA subsequence joined to (ii) a second DNA subsequence, wherein the first DNA subsequence encodes the soluble portion of an insoluble human tumor necrosis factor binding protein having an apparent molecular weight of about (a) 55 kilodaltons or (b) 75 kilodaltons on a non-reducing SDS-polyacrylamide gel, wherein the soluble portion is capable of binding to human tumor necrosis factor, and wherein the second DNA subsequence encodes all of the domains, other than the first domain, of the constant region of the heavy chain of a human immunoglobulin.

Claim 84 recites:

> A DNA encoding a chimeric protein prepared by a process which comprises joining a first DNA subsequence to a second DNA subsequence, wherein the first DNA subsequence encodes the soluble portion of an insoluble human tumor necrosis factor binding protein having an apparent molecular weight of about (a) 55 kilodaltons or (b) 75 kilodaltons on a non-reducing SDS-polyacrylamide gel, wherein the soluble portion is capable of binding to human tumor necrosis factor, and wherein the second DNA subsequence encodes all of the domains, other than the first domain, of the constant region of the heavy chain of a human immunoglobulin.

Claims 100-104 recite:

> A method of making a recombinant DNA construct encoding a chimeric polypeptide comprising fusing a first DNA sequence which encodes a soluble fragment of an insoluble human TNF receptor having an apparent molecular weight of about 55 kilodaltons or about 75 kilodaltons on a non-reducing SDS-polyacrylamide gel to a second DNA sequence which encodes all domains except the first

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incorrect the Examiner is asked to reissue the restriction requirement to clearly set forth which claims are found in each group.

> domain of the constant region of the heavy chain of a human immunoglobulin.

Claims 110-114 recite:

> A chimeric protein encoded by a recombinant DNA construct comprising a first DNA sequence fused to a second DNA sequence wherein the first DNA sequence encodes a soluble fragment of an insoluble human TNF receptor having an apparent molecular weight of about 55 kilodaltons or about 75 kilodaltons on a non-reducing SDS-polyacrylamide gel and the second DNA sequence encodes all domains except the first domain of the constant region of the heavy chain of a human immunoglobulin.

Claims 115-119 recite:

> A method of making a chimeric protein comprising:
> (a) providing a vector comprising a recombinant DNA construct comprising a first DNA sequence fused to a second DNA sequence wherein the first DNA sequence encodes a soluble fragment of an insoluble human TNF receptor having an apparent molecular weight of about 55 kilodaltons or about 75 kilodaltons on a non-reducing SDS-polyacrylamide gel and the second DNA sequence encodes all domains except the first domain of the constant region of the heavy chain of a human immunoglobulin;
> (b) transforming a prokaryotic or eukaryotic host system with the vector;
> (c) cultivating the host system; and
> (d) isolating the chimeric protein from the host system or its culture supernatant.

Claims 120-124 recite chimeric proteins produced by the methods of claims 115-119, respectively.

Claims 100-104 and 110-124 all specifically recite the recombinant DNA recited in claims 68 and 84. A "first DNA sequence fused to a second DNA sequence wherein the first DNA sequence encodes a soluble fragment of an insoluble human TNF receptor having an apparent molecular weight of about 55 kilodaltons or about 75 kilodaltons on a non-reducing SDS-polyacrylamide gel and the second DNA sequence encodes all domains except the first domain of the constant region of the heavy chain of a human immunoglobulin." (Claims 110 and 115.) Specifically, claims 100-104

recite a method of making the DNA of claims 68 and 84; claims 110-114 recite the chimeric protein encoded by the DNA of claims 68 and 84; claims 115-119 recite a method of making a chimeric protein using vector containing the DNA of claims 68 and 84; and claims 120-124 recite a chimeric protein produced by a method using a vector containing the DNA of claims 68 and 84.

Claims 68 and 84 have already been searched and examined. *See* Paper No. 29. Indeed, the Examiner himself has noted that there has already been an "action on the merits" for those claims. *See* Paper No. 31 at 3. Specifically, the Examiner rejected claims 68 and 84 under § 112 for alleged lack of written description and under § 103(a) as allegedly obvious over the combination of two references. *See* Paper No. 29 at 2-5.

In examining claims 68 and 84 the Examiner was required to conduct a thorough search of the prior art:

> In the examination of an application for patent, ***an examiner must conduct a thorough search of the prior art***. Planning a thorough search of the prior art requires three distinct steps by the examiner: (A) identifying the field of search; (B) selecting the proper tool(s) to perform the search; and (C) determining the appropriate search strategy for each search tool selected. Each step is critical for a ***complete and thorough search***.
>
> * * *
>
> ***The search should cover the claimed subject matter and should also cover the disclosed features which might reasonably be expected to be claimed***. The field of search should be prioritized, starting with the area(s) where the invention would most likely be found in the prior art. (MPEP § 904.02, 8th Ed., Rev. 1, February 2003, p. 900-51.) (Emphasis added.)

The Examiner having conducted a search in accord with the above requirements, the DNA constructs recited in claims 68 and 84 have already been thoroughly searched. Claim 68 recites a "DNA sequence which encodes a chimeric protein...," and claim 84 recites a "DNA encoding a chimeric protein...." In addition, claim 84 recites a DNA

"prepared by a process which comprises joining a first DNA subsequence to a second DNA subsequence...."

Thus, a "complete and thorough search" of the subject matter of claims 68 and 84, and of "the disclosed features which might reasonably be expect to be claimed," has already included a search of the method of making the DNA, a search of the method of making the chimeric protein encoded by the DNA, and a search of the chimeric protein encoded by the DNA. This is exactly what is recited in claims 100-104 and 110-124. Accordingly, the examination of claims 100-104 and 110-124 does not require any additional search, and therefore, their introduction imposed no additional burden on the Examiner.

Because examination of all the pending claims would not impose a serious burden on the Examiner, the examination of claims 100-104 and 110-124 is not barred by the alleged constructive election and the withdrawal of claims 100-104 and 110-124 was procedurally improper. For this reason, withdrawal of the restriction and examination of all pending claims is respectfully requested.

In addition, applicants traverse the restriction requirement and requirement for election of species for the following reasons: i) the restriction requirement is deficient for failing to provide evidence that each of the inventions is independent or distinct from the other inventions; ii) the restriction requirement fails to provide adequate evidence that there is a serious burden on the Examiner if the restriction is not made; iii) the requirement for election of species is devoid of any of the evidence or reasoning required to support such a requirement; and iv) the Examiner has offered no evidence or reasoning to support the requirement to elect one member of the recited Markush group for prosecution.

> Under the statute an application may properly be required to be restricted to one of two or more claimed inventions ***only if they are able to support separate patents and they are either independent*** (MPEP § 806.04 - § 806.04(i)) ***or distinct*** (MPEP § 806.05 - § 806.05(i)).
>
> ***If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits***, even though it includes claims to

> independent or distinct inventions. (MPEP § 803, 8th Ed., Rev. 1, February 2003, pp. 800-3 to 800-4.) (Emphasis added.)

Initially, we note that the restriction requirement is completely silent as to the relationships between Inventions II and III, Inventions II and IV, and Inventions I and IV. The restriction requirement, however, asserted that there were four independent or distinct inventions. Having failed to explain the relationships between the other allegedly distinct or independent inventions, the restriction requirement, therefore, fails to demonstrate that there are four independent or distinct inventions. It is respectfully submitted that the restriction requirement is deficient because it fails to even allege that Inventions I-IV are all independent or distinct from one another and should therefore be withdrawn.

Moreover, the Patent Office asserted that Inventions I and III "are distinct because they are structurally and functionally different and have different uses." (Paper No. 31 at 2.) The restriction requirement, however, offers nothing more than the Examiner's subjective conclusion of distinctiveness. The Examiner asserted that the "nucleic acids can be used in nucleic acid hybridization assays while the proteins can [be] used in immunoassays to detect antibodies." (*Id.*) The Patent Office concluded "[t]herefore they are novel and unobvious in view of each other and are patentably distinct." (*Id.*)

That nucleic acids and proteins have different uses is not *per se* evidence of novelty and/or nonobviousness. Merely asserting that a DNA and a protein may have different uses does not *ipso facto* establish that the DNA and protein are patentably distinct and that they must be restricted to separate applications. A single compound may have various uses, *e.g.*, a protein may be used in an immunoassay and in a vaccine. That observation, however, does not lead to the conclusion that the protein is novel and unobvious in view of itself. Paradoxically, it is this logically unsound standard which the Office Action propounds.

Simply put, noting that two products may be used for different purposes does not support an allegation that the products are patentably distinct from one another and that they must be restricted to separate applications. What is

determinative here is what is claimed, and as discussed above, the claimed subject matter has already been searched. Accordingly, the Patent Office has failed to demonstrate that Inventions I and III are distinct from one another. It is respectfully submitted that the restriction requirement is deficient for this additional reason and should be withdrawn.

Furthermore, the Patent Office also failed to provide any evidence that any additional search and examination of all claims cannot be made without serious burden. The MPEP, however, makes it absolutely clear that restriction is improper unless there is such serious burden on the Examiner without restriction.

> If the search and examination of an entire application can be made ***without serious burden, the examiner must examine it on the merits***, even though it includes claims to independent or distinct inventions. (MPEP § 803 at p. 800-4.) (Emphasis added.)

Moreover, the MPEP instructs that various means may be employed to demonstrate this serious burden and that criteria for election of species and Markush groups is set forth separately.

> For purposes of the initial requirement, ***a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation of separate classification***, or separate status in the art, or a different field of search as defined in MPEP § 808.02. That *prima facie* showing may be rebutted by appropriate showings or evidence by the applicant. Insofar as the criteria for restriction practice relating to Markush-type claims is concerned, the criteria is set forth in MPEP § 803.02. Insofar as the criteria for restriction or election practice relating to claims to genus-species, see MPEP § 806.04(a) - § 806.04(i) and § 808.01(a). (*Id.*)

While the Office Action sets out a class and subclass for each of the allegedly distinct inventions (in the case of Invention I two classes and subclasses), no explanation of separate classification is offered. The mere recitation of a class and subclass for the Inventions does not itself demonstrate a separate classification or that such classification results in a serious burden on the Examiner in examining the

allegedly distinct Inventions. For this additional reason the restriction requirement is deficient and should be withdrawn.

The Office Action asserted that Inventions I, II, and IV would all be found in class 435 (CHEMISTRY: MOLECULAR BIOLOGY AND MICROBIOLOGY). Accordingly, these three allegedly distinct inventions do not, on their face, have different classifications, and the Patent Office has not alleged otherwise.

The Patent Office asserted that Invention II would be found in class 435/subclass 91.1 which specifically instructs an Examiner to "SEE OR SEARCH CLASS: 536, Organic Compounds, subclasses 22.1+ for nucleic acids, per se, and for methods of making nucleic acids which do not involve use of an enzyme or microorganism in the process." *See* Exhibit A for the subclass definition from the Manual of Patent Classification (December 2002). The Patent Office asserted that Invention I would be found in class 536/subclass 23.4 (DNA or RNA encoding fusion proteins). Accordingly, a search for Invention II would encompass, at least in part, a search for Invention I.

Likewise, the Office Action asserted that Invention IV would be found in class 435/subclass 69.7 which specifically instructs an Examiner to "SEE OR SEARCH CLASS: 530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclasses 300+ for the product produced by the processes of this subclass." *See* Exhibit B for the subclass definition from the Manual of Patent Classification (December 2002). The Office Action asserted that Invention III would be found in class 530/subclass 387.3 (Chimeric, mutated, or recombined hybrid proteins). Accordingly, a search for Invention IV would encompass a search for Invention III.

The Patent Office asserted that three of the four inventions would be found in the same class (435). Moreover, the Manual of Patent Classification instructs that one searching the subclass asserted for Invention II should search the subclass allegedly containing Invention I and one searching the subclass asserted for Invention IV should search the subclass allegedly containing Invention III. Accordingly, the Patent Office's classification of the allegedly distinct invention does not, by itself,

demonstrate that the search of the entire application would result in a "serious burden" absent the asserted restriction.

As noted above, a "complete and thorough search" of the subject matter of previously examined claims 68 and 84 and "the disclosed features which might reasonably be expect to be claimed," as required, would have included a search of the method of making the DNA, a search of the method of making the chimeric protein encoded by the DNA, and a search of the chimeric protein encoded by the DNA. This is exactly what is recited in Inventions II-IV (claims 100-104 and 110-124). Accordingly, the examination of Inventions II-IV does not require any additional search, and therefore, the introduction of claims 100-104 and 110-124 imposed no serious burden on the Examiner.

In a case such as this, however, "the search and examination of an entire application can be made without serious burden, [and] the examiner must examine it on the merits...." (MPEP § 803 at p. 800-4.) It is respectfully submitted that the restriction requirement is deficient for these additional reasons and should be withdrawn.

It is also respectfully submitted that the additional requirement to elect a species for prosecution is also unwarranted and should be withdrawn.

> Species, while usually independent, may be related under the particular disclosure. Where inventions as disclosed and claimed are both (A) species under a claimed genus and (B) related, then the question of restriction must be determined by both the practice applicable to election of species and the practice applicable to other types of restrictions such as those covered in MPEP § 806.05 - § 806.05(i). ***If restriction is improper under either practice, it should not be required.*** (MPEP § 806.04, 8th Ed., Rev. 1, February 2003, p. 800-40.) (Emphasis added.)

In the present case, the species under restriction are "human immunoglobulins ... selected from the group consisting of IgG, IgA, IgM, and IgE." Claims 102, 112, and 117. Accordingly, the inventions are "(A) species under a claimed genus and (B) related." The Patent Office is, therefore, required demonstrate that the election of species is proper under both election of species practice (MPEP §§ 806.04 -

806.04(i)) and under practice for other types of restriction (MPEP §§ 806.05 - 806.05(i)).

The complete requirement for election of species reads:

> This application contains claims directed to the following patentably distinct species of the claimed invention:
> A recombinant DNA wherein the human Ig is selected from the group consisting of IgG, IgA, IgM or IgE.
> If applicant elects IgG, then a further species election is required between IgG1 or IgG3.
> The applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. (Paper No. 31 at 3.)

Thus, the requirement for election of species is merely an unsupported conclusion that the species are distinct. As such, it does not, indeed it cannot, meet the Patent Office's burden to demonstrate that the election of species is proper under both the election of species practice and the practice for other types of restriction. It is respectfully submitted that the election of species requirement is deficient for this reason alone and should be withdrawn.

In addition, the human immunoglobulins are recited in the claims in the form of a Markush group. The restriction of the members of a Markush group is specifically addressed in the MPEP:

PRACTICE RE MARKUSH-TYPE CLAIMS

> ***If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits***, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction.
>
> Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and *In re Haas,* 580 F.2d 461, 198 USPQ 334 (CCPA 1978), ***it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention***. *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. (MPEP § 803.02, 8th Ed., Rev. 1, February 2003, pp. 800-4 to 800-5.)

To properly restrict examination to a single member of a Markush group, it is incumbent on the Patent Office to make two showings: First, that the members of the Markush group are not "sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden." And second, that the "subject matter lacks unity of invention." The Patent Office has shown neither.

The requirement for election of species is devoid of any discussion of the size of the Markush group or the relationship of its members to one another. The recited Markush group, however, contains only four structurally related members. Moreover, the Examiner has not asserted, much less demonstrated, that the subject matter defined by the Markush group lacks unity of invention. In fact, the members of the Markush group share a common utility due to their structural similarity. Accordingly, the Patent Office has failed to meet its burden to show that the requirement for election of a single member of the Markush group is proper. For this additional reason, the

requirement for election of species is deficient and its withdrawal is respectfully requested.

Accordingly, for the reasons set forth above, withdrawal of the constructive election, restriction requirement, and requirement for election of species, and examination of all pending claims on the merits are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

No further fee, other than for a five-month extension of time, is required in connection the filing of this Communication. If any additional fees are deemed necessary, authorization is given to charge the amount of any such fee to Deposit Account No. 08-2525.

Respectfully submitted,

By:_____

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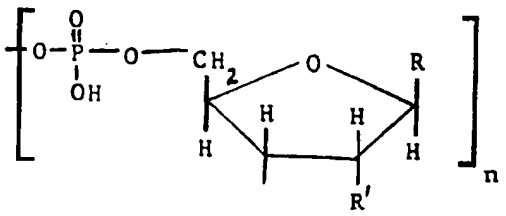
91.1 Polynucleotide (e.g., nucleic acid, oligonucleotide, etc.):

This subclass is indented under subclass 89. Processes wherein the product synthesized is (see image below) where "n" is a whole number greater than 2, R' is H or OH, and R is purine or pyrimidine or a substituted purine or pyrimidine.



(1) Note. The two purines, adenine and guanine, are found in both deoxyribonucleic acid (DNA) and ribonucleic acid (RNA). The pyrimidine cytosine is found in both DNA and RNA while the pyrimidine thymine is found only in DNA and the pyrimidine uracil appears only in RNA.

(2) Note. This and the indented subclasses are intended to include processes wherein the polynucleotide synthesized did not exist as such in the starting material. The synthesized material may be entirely different from the starting material, or it may have a substituted, deleted, or added nucleotide or nucleotides.

(3) Note. Substituted purine or pyrimidine includes only those derivatives which are substituted on, rather than in the respective ring positions.

(4) Note. If the disclosure is unclear as to what kind of polynucleotide is being made (i.e., RNA or DNA) the subject matter should be classified in the first appearing appropriate subclass for either RNA or DNA and cross-referenced to other appropriate subclasses for RNA or DNA. Unless the subject matter is directed to an acellular amplification process, synthesis of RNA is intended for subclasses 91.3+.

SEE OR SEARCH THIS CLASS, SUBCLASS:

91.3+, for processes wherein the product synthesized contains only ribonucleotide monomers.

270, for methods of removing nucleic acid from intact or disrupted cells by the use of an enzyme or microorganism.

SEE OR SEARCH CLASS:

536, Organic Compounds, subclasses 22.1+ for nucleic acids, per se, and for methods of making nucleic acids which do not involve use of an enzyme or microorganism in the process.

91.2 Acellular exponential or geometric amplification (e.g., PCR, etc.):

This subclass is indented under subclass 91.1. Processes which result in a geometric or exponential increase in the number of copies of a nucleotide sequence or sequences, rather than an arithmetic increase which occurs in the making of a single complementary copy of a nucleotide, wherein such processes take place without the involvement of viruses, eukaryotic cells, or prokaryotic cells.

(1) Note. Included in this subclass is the polymerase chain reaction (PCR). PCR is an in vitro DNA amplification system that uses repeated cycles of oligonucleotide-directed DNA synthesis to selectively generate multiple copies of a specific DNA segment. It involves repeated cycles of (a) denaturation or strand displacement of the DNA, (b) annealing of two oligonucleotide primers that flank the DNA segment to be amplified, and (c) extension of the annealed primers with DNA polymerase.

(2) Note. Processes which result in an arithmetic increase in the number of copies of a nucleotide sequence, such as occurs in the making of a single complementary copy of a nucleotide sequence, are proper for subclasses 91.3+ if the nucleotide is a ribonucleotide and either subclass 91.1 or subclasses 91.5+, depending on the process details, if the nucleotide is other than a ribonucleotide.

SEE OR SEARCH CLASS:
530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclass 399 for the product produced by the processes of this subclass.

69.5 Lymphokines or monokines:
This subclass is indented under subclass 69.1. Processes wherein the product synthesized is a lymphokine or monokine.

(1) Note. Examples of the subject matter included in this subclass are cloning and expression of interferon, interleukin, lymphotoxin, or tumor necrosis factor.

SEE OR SEARCH CLASS:
424, Drug, Bio-Affecting and Body Treating Compositions, subclass 85 for bioactive compositions containing interferon.
530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclass 351 for the product produced by the processes of this subclass.

69.51 Interferons:
This subclass is indented under subclass 69.5. Processes wherein the product synthesized is an interferon.

SEE OR SEARCH CLASS:
424, Drug, Bio-Affecting and Body Treating Compositions, subclass 85 for compositions of that class containing interferon.
514, Drug, Bio-Affecting and Body Treating Compositions, subclass 21 for compositions of that class containing interferon.
530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclass 351 for the product produced by the processes of this subclass.

69.52 Interleukins:
This subclass is indented under subclass 69.5. Processes wherein the product synthesized is an interleukin.

SEE OR SEARCH CLASS:
514, Drug, Bio-Affecting and Body Treating Compositions, subclass 21 for compositions of that class containing an interleukin.
530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclass 351 for the product produced by the processes of this subclass.

69.6 Blood proteins:
This subclass is indented under subclass 69.1. Processes wherein the product synthesized is a blood protein.

(1) Note. Examples of the subject matter included in this subclass are cloning and expression of polypeptide of immunoglobulin origin.

SEE OR SEARCH THIS CLASS, SUBCLASS:
70.4, for processes including the culture of blood cells.

SEE OR SEARCH CLASS:
424, Drug, Bio-Affecting and Body Treating Compositions, subclasses 85.1+ for composition of that class containing a blood protein.
514, Drug, Bio-Affecting and Body Treating Compositions, subclasses 2+ for compositions of that class containing a blood protein.
530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclasses 380 through 394 for the product produced by the processes of this subclass.

69.7 Fusion proteins or polypeptides:
This subclass is indented under subclass 69.1. Processes wherein the product synthesized is a fusion protein or fusion polypeptide.

(1) Note. Examples of the subject matter included in this subclass are the cloning and expression of a fused polypeptide (e.g., tribrid protein).

SEE OR SEARCH CLASS:
530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclasses 300+ for the product produced by the processes of this subclass.

69.8 **Signal sequence (e.g., beta-galactosidase, etc.):**
This subclass is indented under subclass 69.1. Process wherein the product synthesized is a protein or polypeptide with a signal sequence such as beta-galactosidase.

SEE OR SEARCH THIS CLASS, SUBCLASS:
183, through 234, for enzymatic signal sequences.

SEE OR SEARCH CLASS:
530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclasses 300+ for the product produced by the processes of this subclass which includes fused polypeptides.

69.9 **Yeast derived:**
This subclass is indented under subclass 69.8. Processes wherein the product synthesized is a protein or polypeptide with a yeast derived signal sequence.

(1) Note. Examples of the subject matter included in this subclass are cloning and expression of polypeptides attached to a yeast signal sequence (e.g., alpha-amylose).

SEE OR SEARCH THIS CLASS, SUBCLASS:
183, through 234, for enzymatic signal sequence of yeast.

SEE OR SEARCH CLASS:
530, Chemistry: Natural Resins or Derivatives Peptides or Proteins; Lignins or Reaction Products Thereof, subclasses 300+ for the product produced by the processes of this subclass which include fused polypeptides.

70.1 **Using tissue cell culture to make a protein or polypeptide:**
This subclass is indented under subclass 41. Processes wherein an in vitro tissue cell culture is used to produce a protein or polypeptide.

(1) Note. An example of the subject matter included in this subclass is use of a plant or animal cell culture to produce polypeptides.

(2) Note. See this class, subclass 68.1 for the definition of polypeptide or protein.

SEE OR SEARCH THIS CLASS, SUBCLASS:
325+, for the culture of animal cells absent the production of a protein or polypeptide product.

SEE OR SEARCH CLASS:
930, Peptide or Protein Sequence, subclasses 10+ for peptide or protein sequence of four or more amino acids.

70.2 **Fused or hybrid cells:**
This subclass is indented under subclass 70.1. Processes wherein the product is synthesized by culture of fused or hybrid cells.

(1) Note. Fused or hybrid cells include those resulting from (a) the fusion of two cells, (b) the insertion of the nucleus or chromosone of one cell into another or (c) the treatment of a cell with an immortalizing agent which results in a cell which will proliferate in long-term culture.

(2) Note. Examples of the subject matter included in this and the indented subclass are use of lymphoblastoid hybridoma cells to produce peptide hormones (e.g., insulin, calcitonin, growth hormone, etc.) or monoclonal anti-bodies or use of cells transformed with a virus or oncogene to produce a cell line which will proliferate and produce proteins or polypeptides in long term culture.